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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,705	01/29/2004	Jacques Dubois	9404.0008-05	5654

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EXAMINER	
WEDDINGTON, KEVIN E	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 02/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/767,705	DUBOIS ET AL.	
	Examiner	Art Unit	
	Kevin E. Weddington	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,8 and 12-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,8 and 12-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 3, 8 and 12-38 are presented for examination.

Applicants' preliminary amendment filed January 29, 2004 and the information disclosure statements filed January 29, 2004; June 29, 2004; and October 26, 2004 have been received and entered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3, 8 and 12-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,262,071. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application teaches a method of treating or preventing a bacterial infection by maxillary sinus pathogenic bacteria comprising the step of administering an antibacterially effective amount of a composition comprising a gemifloxacin compound; and the patented application teaches a method for modulating metabolism (inhibit the growth) of Mycoplasma bacteria which falls within the scope of the present application's method of preventing a bacterial infection caused by maxillary sinus pathogenic bacteria which includes Mycoplasma strains (claims 3 and 13) with the administration of a gemifloxacin compound and its pharmaceutically acceptable salts since modulating metabolism (to inhibit the growth or prevent the growth) and preventing are same.

Claims 3, 8 and 12-38 are not allowed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman,* 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi,* 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum,* 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3, 8 and 12-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-13 of U.S. Patent No. 6,803,376. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application teaches a method of treating or preventing a bacterial infection by maxillary sinus pathogenic bacteria comprising the step of administering an antibacterially effective amount of a composition comprising a gemifloxacin compound; and the patented application teaches a method of treating or preventing a bacterial infection by pneumococcal pathogenic bacteria comprising the step of administering an antibacterially effective amount of a gemifloxacin compound falls within the scope of the present application's method of treating or preventing a bacterial infection caused by maxillary sinus pathogenic bacteria which includes Streptococcus pneumoniae (claims 3 and 15) with the administration of a gemifloxacin compound and its pharmaceutically acceptable salts.

Claims 3, 8 and 12-38 are not allowed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman,* 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi,* 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum,* 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3, 8 and 12-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,331,550. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application teaches a method of treating or preventing a bacterial infection by maxillary sinus pathogenic bacteria comprising the step of administering an antibacterially effective amount of a composition comprising a gemifloxacin compound; and the patented application teaches a method for modulating metabolism (inhibit the growth) of anaerobic pathogenic bacteria comprising the step of contacting the said pathogenic bacteria with an antibacterially effective amount of a gemifloxacin compound too. Note the patented application's method for modulating metabolism (inhibit the growth) of anaerobic pathogenic bacteria which falls within the scope of the present application's method of preventing a bacterial infection caused by maxillary sinus pathogenic bacteria which includes anaerobic bacteria with the administration of a gemifloxacin compound and its pharmaceutically acceptable salts since modulating metabolism (to inhibit the growth or prevent the growth) and preventing are the same.

Claims 3, 8 and 12-38 are not allowed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3, 8 and 12-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 5-7 and 9-12 of copending Application No. 10/742,679. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application teaches a method of treating or preventing a bacterial infection by maxillary sinus pathogenic bacteria comprising the step of administering an antibacterially effective amount of a composition comprising a gemifloxacin compound; and the copending application teaches a method for modulating metabolism (inhibit the growth) of maxillary sinus pathogenic bacteria comprising the step of contacting maxillary sinus pathogenic bacteria with an antibacterially effective amount of a gemifloxacin compound too. Note the copending application's method for modulating metabolism (inhibit the growth) of maxillary sinus pathogenic bacteria falls within the scope of the present application's method of preventing a bacterial infection caused by maxillary sinus pathogenic bacteria with the administration of a gemifloxacin compound and its pharmaceutically acceptable salts since modulating metabolism (to inhibit the growth or prevent the growth) and preventing are the same.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 3, 8 and 12-38 are not allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 8 and 12-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating bacterial infections caused by maxillary sinus pathogenic bacteria with gemifloxacin, does not reasonably provide enablement for any and all gemifloxacin compounds and its salts or other fluoroquinolone compounds or preventing a bacterial infection by maxillary sinus pathogenic bacteria by administering a gemifloxacin compound. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to a method of treating or preventing a bacterial infection by maxillary sinus pathogenic bacteria comprising the step of contacting maxillary sinus pathogenic bacteria with an antibacterially effective amount of a composition comprising a gemifloxacin compound.

The relative skill of those in the art is generally that of a Ph.D. or M.D.

The present invention is unpredictable unless experimentation is shown for the other gemifloxacin compound to treat maxillary sinus pathogenic bacteria.

There are no known preventive therapies for bacterial infections caused by maxillary sinus pathogenic bacteria.

It is clear the art to which the present invention relates is highly unpredictable and unreliable with respect to conclusions drawn from laboratory data extrapolated to clinical efficacy.

The breadth of the claims

The claims are very broad and inclusive to all gemifloxacin typed compounds or other fluoroquinolone compounds.

The amount f direction or guidance provided and the presence or absence of working examples

The working examples are limited only to gemifloxacin showing superior results against maxillary sinus pathogenic bacteria over the other fluoroquinolone compounds.

There are no examples showing "a gemifloxacin compound" will, in fact, prevent bacterial infections caused by maxillary sinus pathogenic bacteria especially in a mammal not presently at risk or predisposed to developing such an infection.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to how the other gemifloxacin compounds are effective in treating bacterial infections caused by maxillary sinus pathogenic bacteria. The level of experimentation needed to determine the other related gemifloxacin compounds would be able to kill or control maxillary sinus pathogenic bacteria is undue.

Applicants also failed to provide guidance as to which particular bacteria of maxillary sinus pathogenic bacteria would be prevented. The skilled artisan would expect that interaction of a particular drug in the prevention of maxillary sinus pathogenic bacteria to be very specific and highly unpredictable absent a clear understanding of the structural and biochemical basis of the agent. The instant specification set forth no such understanding or any criteria for extrapolating beyond administration of gemifloxacin or a gemifloxacin typed compound to prevent the said bacterial infections. Even for the data prevented, no direction is provided to prevent bacterial infections by maxillary sinus pathogenic bacteria. Absent reasonable *a priori* expectations of success, one skilled in the art would have to test extensively many maxillary sinus pathogenic bacteria that may lead to bacterial infections to discover which maxillary sinus pathogenic bacteria is prevented. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as its is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

Claims 3, 8 and 12-38 are not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3, 8 and 12-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/42705 (BA of PTO-1449), hereby known as Kim et al., EP 0,688,722 (BB of PTO-1449), hereby known as Kwak et al., Berger-Neel et al, (4,931,446 or AE of PTO-1449) and Copeland et al. (5,756,506 or AF of PTO-1449).

The four primary references teach fluoroquinolones as having antibacterial activities. Note each reference teaches the active fluoroquinolones including gemifloxacin effective against various bacteria that causes various bacterial infections (See the abstract of each individual reference).

The instant invention differs from the cited references in that the cited references do not teach instant fluoroquinolones such as gemifloxacin are used to treat bacterial infections caused by maxillary sinus pathogenic bacteria. However, one skilled in the art would have assumed that the antibacterial

compounds of the cited references would be effective against any bacteria in the absence of evidence to the contrary.

Claims 3, 8 and 12-38 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0953. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
February 15, 2005